MAY 1 8 2000

K000779 p.1/2

510(k) Summary of Safety and Effectiveness

Date:

March 10, 2000

Submitter:

GE Marquette Medical Systems
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems
Phone: (414) 362-2090
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Device: Trade Name:

ApexPro Telemetry System

Common/Usual Name:

Telemetry Monitoring System

Classification Names:

21 CFR 870.1025 Detector and Alarm, Arrhythmia

21 CFR 870.2910 Transmitters and Receivers, Physiological Signal, Radio Frequency

Predicate Devices:

K891104 CD Telemetry Systems
K980299 Apex Oximeter

Device Description:

The ApexPro Telemetry System is composed of six major components:

- The patient worn data acquisition transmitters
- The receiver antenna system infrastructure
- The Receivers
- The Receiver Subsystem
- A computer platform running the ApexPro Telemetry Application
- A computer platform running a central station application (which may be the same computer platform running the ApexPro Telemetry Application).

Intended Use:

The ApexPro Telemetry System is intended for use under the direct supervision of a licensed healthcare practitioner. The system is designed to acquire and monitor physiological data for ambulating patients within a defined coverage area. The system processes this physiological data to detect various ECG arrhythmia events and select physiological parameter limit violations.

The ApexPro Telemetry System is intended to be installed in the hospital or clinical environment in order to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive

blood pressure, and SpO_2. Received data will be sent to the computer platform for ECG processing via Ethernet. It is also intended to provide physiologic data over the Unity network to clinical information systems.

Technology:

The ApexPro employs the same functional technology as the predicate devices. The system architecture has taken advantage of improvements in signal processing technology as well as advances in RF component technologies to improve performance and level of integration.

Test Summary:

The ApexPro complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the ApexPro System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 8 2000

Mr. David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems
8200 W. Tower Ave.
Milwaukee, WI 53223

Re: K000779
Trade Name: ApexPro Telemetry System
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: March 9, 2000
Received: March 10, 2000

Dear Mr. Wahlig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K000779

510(k) Number (if known): Unknown; 510(k) filed on August 24, 1999

Device Name: ApexPro Telemetry System

Indications For Use:

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The ApexPro Telemetry System is intended for installation in the hospital or clinical environment to provide clinicians with patient physiological data, while allowing for patient mobility. These systems are typically deployed in sub acute care areas in hospitals or clinical sites where patient mobility can enhance the effectiveness of the medical procedures administered.

The physiological parameters monitored include ECG, non-invasive blood pressure, and SpO_2. Received data will be sent to the computer platform for ECG processing via Ethernet. It is also intended to provide physiologic data over the Unity network to clinical information systems. This information can be displayed, trended, stored, and printed.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K000779

5/17/00